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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,552	08/30/2001	Koji Kishi		9691

7590

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/914,552**

Applicant(s)  
**Kishi et al.**

Examiner  
**Ralph Gitomer**

Art Unit  
**1651**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 4, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 14-26 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 14-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 6) ☐ Other:

Please update the specification to related cases such as the Japanese patent from which priority is claimed. Priority is granted to March 1, 1999. Claims 1-7, 14-26 are currently pending in this application. No foreign search report is found in the file, a copy is requested.

The presently claimed invention is directed to combinations of assaying for cholesterol fractions by controlling the reactivity of an enzyme by changing the ionic strength, a surfactant, or using an enzyme specific to the fraction.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 6, 15, 21, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Nakamura, Miki (102(a)) and Sugiuchi.

Nakamura (6,057,118) entitled ~~Method~~ Method for Quantitatively Determining LDL Cholesterol~~s~~ teaches in the claims, determining LDL with a surfactant, a polyanion, with cholesterol esterase and cholesterol oxidase.

5 Miki (5,925,534) entitled ~~Method~~ Method for Measuring LDL Cholesterol~~s~~ teaches in the claims, determining LDL with a surfactant and a polyanion.

10 Sugiuchi (Clinical Chemistry) entitled ~~Homogeneous~~ Homogeneous Assay For Measuring Low Density Lipoprotein Cholesterol in Serum with Triblock Copolymer and Cyclodextrin Sulfate~~s~~ teaches in the abstract, determining LDL with POE-POP surfactant changes reactivity of lipoprotein fractions. Cyclodextrin selectively reduced reactivity of cholesterol for determining LDL.

15 Each of the features of the claims are taught by each of the above references for the same function as claimed. Regarding claim 26 directed to performing the assay at an optimum pH, it is well known in this art to select pH ranges for desired enzymatic reactions expected to occur in a reproducible manner.

20 Claims 3, 5, 7, 14, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Yamauchi and Kerscher.

25 Yamauchi (Rinsho Kagaku) entitled ~~Evaluation~~ Evaluation of Reactivity Using Direct Assay Methods for High Density Lipoprotein Cholesterol~~s~~ teaches in the abstract, determining HDL with PEG modified enzymes or a polyanion and surfactant as compared to a

precipitation method.

Kerscher (4,892,815) entitled ❖Process and Reagent for the Specific Determination of the Cholesterol of the HDL Fraction❖ teaches in column 2 lines 38-45, detergents and enzymes to  
5 determine HDL. See the claims.

Each of the features of the claims are taught by each of the above references for the same function as claimed.

10 Claims 16-19, 22-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Nakamura.

Nakamura (6,057,118) entitled ❖Method for Quantitatively Determining LDL Cholesterols❖ teaches in the claims, determining LDL with a surfactant, a polyanion, with cholesterol esterase and cholesterol oxidase. In column 3 various methods of determining  
15 VLDL are shown with polyanion and surfactants.

Each of the features of the claims are taught by Nakamura for the same function as claimed.

20 Claims 2-7, 15-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

The dependent claims must begin with a definite article. In claim 18 and all occurrences, ~~the~~ have the cholesterol component remained~~is~~ is not understood in context.

5 The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

10 The following prior art pertinent to applicant's disclosure is made of record and not relied upon:  
Gedik, Nursal, entitled ~~Direct~~ Direct Measurement of HDL Cholesterol in Serum with Polyethylene Glycol Modified Enzymes Cholesterol Esterase and Cholesterol Oxidase~~,~~, Biyokim Derg 1998, 23(1)10-17 teaches measuring HDL cholesterol with modified enzymes that show  
15 selective catalytic activities in the presence of Mg+2. No copy of this article is presently available.  
Kishi (6,114,134) teaches determining HDL.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the  
25 examiner's supervisor, Michael Wityshyn can be reached on (703)

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308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button Patent Electronic Business Center for more information.

*Ralph Gitomer*  
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